

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 66267-0011		Date of mailing (day/month/year) 21 JUN 2005
International application No. PCT/US05/04291		FOR FURTHER ACTION See paragraph 2 below International filing date (day/month/year) 11 February 2005 (11.02.2005) Priority date (day/month/year) 11 February 2004 (11.02.2004)
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61B 5/0468, 5/0472 and US Cl.: 600/509, 516		
Applicant HENRY FORD HEALTH SYSTEM		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
☐ Box No. II Priority
☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐ Box No. IV Lack of unity of invention
☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐ Box No. VI Certain documents cited
☐ Box No. VII Certain defects in the international application
☐ Box No. VIII Certain observations on the international application

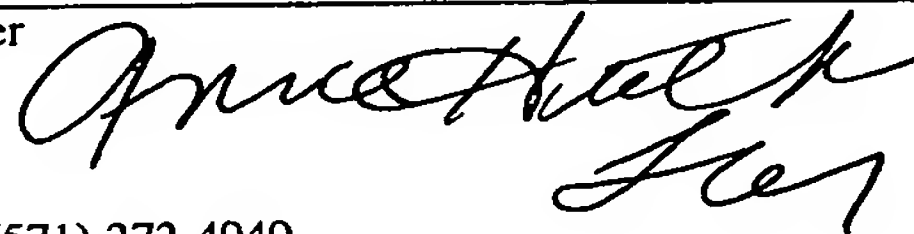
2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Carl H. Layno  Telephone No. (571) 272-4949
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US05/04291

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>4, 8-21, 28, 29, and 33-39</u>	YES
	Claims <u>1-3, 5-7, 22-27, and 30-32</u>	NO
Inventive step (IS)	Claims <u>4, 8-21, 28, 29, and 33-39</u>	YES
	Claims <u>1-3, 5-7, 22-27, and 30-32</u>	NO
Industrial applicability (IA)	Claims <u>1-39</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-3, 5-7, 22-27, and 30-32 lack novelty under PCT Article 33(2) as being anticipated by Taha et al '090-B2. The Taha et al '090-B2 patent describes a method and apparatus for the serial comparison of electrocardiograms. Fig.2A shows that a baseline ECG value is acquired from the patient during a stable cardiac period 100. This baseline is stored in system memory 102 and later compared with recently acquired ECG data 108. A plurality of QRS complex segments are compared (Figd.2B and 2C) including QT interval 138. If the QT interval exceeds the baseline and is greater than 450 ms, then a "severity value" is assigned to the QT interval block. If the QT interval exceeds 480 ms, then a "high severity" value is assigned (col.8, lines 40-48). In regard to claim 3, this analysis is performed automatically by management module 26 (Fig.1). In regard to claims 6, 22, and 25, the detection of prolonged QT interval is indicative of acute ischemia (i.e. infarction) (col.8, lines 29-30).

Claims 4, 8-21, 28, 29, and 33-39 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method and corresponding ECG monitoring apparatus capable of performing an electrocardiogram comparison manually (claim 4), comparing activation recovery interval data (claims 8,28,33,38), comparing monophasic action potential data (claims 9,29,34,39), performing an ECG comparisons after a clinical procedure (claims 10-21), or detecting prolonged myocardial repolarization as an indicator of "ischemic preconditioning" (claims 35-39).

Claims 1-39 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.